

**REMARKS**

Claims 1-6 and 8-22 are pending in the present application.

As an initial matter, Applicants request withdrawal of the finality of the previous office action, as the issuance of a final office action by the Examiner was improper. As stated by MPEP 706.07(a):

second or any subsequent actions on the merits shall be final, except where the examiner introduces a new grounds of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(a) with the fee set forth in 37 CFR 1.17(q).

In this case, the Examiner has introduced a new ground of rejection. Specifically, claims 1-6 and 8-22 are now being rejected as being allegedly rendered obvious by U.S. Patent No. 4,743,257 to Tormala (the '257 patent) in view of GB 2085461 (the '461 application). In the previous Office Action of 9/12/03, such a rejection was not presented and therefore the present rejection is a new ground of rejection.

The Examiner stated that Applicants' amendment necessitated this new ground of rejection. However, this is wholly incorrect as the Applicants' amendments of 12/12/03, only corrected issues related to lack of antecedent basis. There was no new subject matter added by way of these amendments that would in anyway necessitate a new ground of rejection. In fact, it seems clear that the reason for these new rejections had nothing to do with Applicants' amendments of 12/12/03, but rather due to the fact that in the first office action, the Examiner rejected these claims in view of references that did not even qualify as prior art. Therefore, if the claims were to be rejected again, new references had to be uncovered and cited against the Applicants in a subsequent office action. Such a subsequent rejection was in no way due to Applicants' amendments of 12/12/03. For these reasons, the Applicants request withdrawal of the finality of the Office Action.

With respect to the present rejections, Applicants submit that claims 1-6 and 8-22 are not rendered obvious by the '257 patent in view of the '461 application or by the '461 application in view of the '257 patent. Specifically, Applicants submit that a *prima facie* case of obviousness has not been made as there is no motivation to combine the references for a number of reasons.

First, the '257 patent relates to osteosynthesis composite materials for absorbable surgical devices. In contrast, the '257 patent relates to composite materials for prosthesis, *i.e.* permanent artificial replacement of parts of the anatomy that are obviously not to be adsorbed by the body. This is particularly evident by the fact that the '461 application makes no mention of biodegradable materials as recited by the '257 patent, since biodegradable materials would not be suitable for prosthetic implants. Accordingly, one skilled in the art would not be motivated to combine the teachings of these two references and replace or add the material described by one reference with or to the material described by the other reference, as these references deal with entirely different applications of composite orthopedic materials.

Second, the Examiner stated that it would have been obvious for one of ordinary skill in the art to include the particulate material of the '461 application in the composite of the '257 patent with an "expectation to increase the strength of the composite material." Alternatively, the Examiner argued that it would have been obvious for one of ordinary skill in the art to prepare a polymer matrix that is reinforced with a polymer as described in the '257 patent and which contains the inorganic particulate material of the '461 application because "the '257 patent teaches that absorbable polymers typically have lower mechanically [sic] strength than compact bone and that reinforcing the matrix with a polymer improves [the mechanical properties] of the composite material." Such an analysis fails to appreciate that each reference already individually provides its own solution to the very problem that the Examiner identified, *i.e.* trying to increase strength of the composite material. There is no motivation to combine the references to solve a problem that has already purportedly been solved by the approaches described in the individual references.

Specifically, the '257 patent describes a polymeric matrix that is reinforced with reinforcement elements which have the same chemical element percentage composition as does the matrix. According to the '257 patent "when strong oriented fiber structures are bound together with the polymer matrix which has the same chemical element composition as the fibers, the composite structure is obtained which has excellent adhesion between the matrix and reinforcement material and therefore also has excellent

mechanical properties." Col. 3, lines 53-62. Therefore, although the Examiner was correct in noting that the '257 discusses the strength deficiencies of prior adsorbable polymers, the '257 patent does so as a prelude to providing a solution to this problem-- using oriented fiber structures bound with a polymer matrix that has the same chemical element composition as the fibers. Accordingly, there is no motivation to strengthen the composite material of the '257 patent with the particulate material of the '461 application, since the '257 patent already describes a composite material that has "excellent mechanical strength properties." Col. 4, line 55-57. Applicants submit that one skilled in the art would have no reason to add a further element to the composite material of the '257 patent to strengthen an already strong material.

Similarly, the '461 application provides a solution to the problem of prosthetic materials not having adequate mechanical strength. The '461 application's solution is using a particulate inorganic solid component to reinforce the composite and to enhance its stiffness. Taking the description of the effects of the particulate material on its face, there is no reason for one of ordinary skill in the art to doubt that this approach produces a composite material that is sufficiently strong, as alleged by the '461 application. Accordingly, one skilled in the art would not be motivated to add another reinforcement phase to an already reinforced composite material as described by the '461 application. For at least the above-mentioned reasons, one of skill in the art would not be motivated to combine the '257 patent and the '461 application to produce the invention as recited in claims 1-6 and 8-22.

Furthermore, even if there were a motivation to combine the '257 patent and the '461 patent, Applicants submit that claims 1-6 and 8-22 are still not rendered obvious by such a combination. Specifically, Applicants submit that the claimed range of particle size of the bioceramic or bioglass reinforcing component of between 2 $\mu$ m and 150 $\mu$ m is critical. Specifically, as Applicants pointed out in the 8/25/03 Response to Office Action, this claimed range achieves unexpected results relative to the prior art. The specification states at page 6, lines 14-22:

[t]he defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites

having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

Therefore, Applicants have shown that particle size of 2  $\mu$ m to 150  $\mu$ m is contrary to conventional practice and renders unexpected benefits, such as greater biocompatibility and less irritation to tissue. For at least this reason, Applicants submit that claims 1-6 and 8-22 are not rendered obvious by the '257 patent and the '461 application in view of each other.


### CONCLUSION

Applicants submit that the subject application is in condition for allowance, and respectfully requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicants' attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,  
KENYON & KENYON

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